Attachment 1

THE AGENCY'S RESPONSE TO COMMENTS ON THE HUMAN HEALTH RISK ASSESSMENT FOR THE METHYL PARATHION

I. INTRODUCTION

The following is the Agency's response to comments (Phase 4) for methyl parathion generated in response to the comments submitted to the public docket by Cheminova Agro A/S, Elf Atochem, the Environmental Working Group, the Natural Resources Defense Council, World Wildlife Fund, and the Consumers Union, in Phase 3 of the Public Participation Process. Some of the responses serve as clarification of Agency policies and guidance and it is hoped that this will provide a greater understanding of the Agency's position and procedures on the respective issues. Issues unrelated to the quantitative risk assessment and characterization cannot be dealt with in the Phase 4 timeframe. The registrants need to work with the Agency on changes and/or clarification of label language before a re-evaluation of the risk can be made.

Since there were a number of comments submitted from very differing sources, the Agency's responses will be directed to the issues raised and not to each of the commentors. In many cases, the same subject matter was raised by several of the commentors but with very different view points.

Following their comments, Cheminova generated the following data to provide additional studies for endpoint selection and dermal absorption. The Agency reviewed the studies and revisited the toxicity endpoints and absorption as appropriate.

1. Valdez-Flores, C. (1998). Statistical reanalysis on a per litter basis on data from "E-605-Methyl. Multigenerational studies on rats" (E. Loser & R. Eiben, 1982, Bayer AG Report No. 10630). Sielken, Inc.;

2. Acute dietary toxicity study in rats (neuropathology included). Summary of results submitted. Final report submitted May 1999;

3. 5-Day dermal toxicity study in rats (neuropathology included). Summary of results submitted. Final full report submission June 1999 (MRID No. 44843601, 44843602);

4. Acute dietary Monte Carlo analysis. Received April 1999.

In addition, Cheminova and Elf Atochem made a number of comments concerning the submission residue chemistry data, which are addressed in Residue Chemistry/Dietary Exposure below.

II. SUPPORTED USE PATTERNS

A. Methyl parathion registrations

EPA acknowledges receipt of clarification of the food/feed use sites, patterns, and restrictions which the registrants (Cheminova, Elf Atochem, and IR-4) wish to support for the reregistration of the EC and Mcap formulations of methyl parathion on food/feed crops. This detailed use information will be carefully considered in the residue chemistry science assessments and dietary risk assessment analyses for the reregistration of methyl parathion.

Any proposed food/feed use patterns that are included in the revised risk assessment will need to be reflected on the labels and will require label changes. The Special Review and Reregistration Division (SRRD) and Registration Division (RD) will work with the registrants in these follow-up activities.

III. TOXICOLOGY

A. General

Cheminova has provided two submissions on the preliminary risk assessment for methyl parathion. Cheminova separated comments on the same general issues into sections addressing specifically the EPA Chapter, Toxicology Chapter, Hazard Identification report, etc. For the purposes of composing a succinct response, related comments have been combined and will be addressed according to the issues raised.

Additional comments related to toxicology and endpoint selection were received from the Consumer's Union (CU), Environmental Working Group (EWG), National Resources Defense Council (NRDC), and the World Wildlife Fund (WWF). Several of these commentors cited evidence of possible endocrine disrupting effects of methyl parathion. WWF submitted copies of several literature articles to support their position regarding potential endocrine disrupting effects of methyl parathion exposure. CU, EWG, and NRDC all agreed with the need for a developmental neurotoxicity study and retention of the 10x FQPA Safety Factor for the protection of infants and children. Discussion regarding possible endocrine disrupting effects of methyl parathion has been incorporated into the Toxicology Chapter.

B. Data submissions and data evaluations

Cheminova is currently conducting new studies to provide more appropriate data for estimating hazard from acute oral and short-term dermal exposures. A description of the preliminary results from these studies was provided in Cheminova's second set of comments. Cheminova has also suggested they may conduct a longer term dermal study to address intermediate term dermal risk. EPA will evaluate the data from these studies when they are

received, and incorporate the findings into the risk assessment as appropriate.

Cheminova submitted several additional studies not available to EPA when the preliminary risk assessment was completed (new rabbit developmental toxicity study, new 1-year dog study, preliminary dermal neurotoxicity data, short-term dermal study, short-term oral study, and new oral and dermal LD_{50} studies with a formulation). [EPA notes that one study cited by Cheminova as submitted with the first set of comments (1982 Loser and Eiben reproduction study) was received by EPA after the close of the comment period.] In addition, Cheminova provided their own analysis of the data from several studies included in the EPA Toxicology Chapter (test substance intake data from the 90-day neurotoxicity study, litter data from the reproduction studies), and commented on an old (supplementary) rat developmental study not included in the human health risk assessment. Upon EPA review of the submitted information, it was found that several of the submitted studies were not complete, or did not contain information likely to impact on the risk assessment. Information which might impact the risk assessment was evaluated in more detail and has been incorporated into the Toxicology Chapter and the risk assessment as appropriate.

Cheminova disagrees with EPA's interpretation of many of the guideline studies described in EPA's Toxicology Chapter and other documents. Cheminova provided alternative interpretations of the data, including arguments concerning the relevance of cholinesterase inhibition in endpoint selection. In addition, Cheminova believes the study selected for chronic dietary risk assessment (Chronic toxicity/carcinogenicity study in rats, Accession Nos. 252501-252503, 253346, 253372-253374), has many weaknesses and should not be used for risk assessment. EPA has noted Cheminova's interpretation of the study summaries. The studies were reviewed in accordance with EPA policy, and have previously undergone internal review. Conclusions in those reviews will not be reevaluated in the context of the current risk assessment/public comment process. In cases where EPA agreed that study conclusions were misrepresented in the Toxicology Chapter, or that statements in the Toxicology Chapter could be easily misinterpreted, EPA has corrected and/or clarified the statements in the Toxicology Chapter. For the most part, the issues raised by Cheminova do not affect the endpoints used for the methyl parathion risk assessment. With regard to the adequacy of the 2-year chronic rat study, if Cheminova feels the current chronic study is inadequate, they are free to submit new chronic toxicity data in the rat.

Cheminova objects to the requirement of a 'confirmatory' neurotoxic esterase (NTE) study, and cites literature data putatively documenting that methyl parathion is not an inhibitor of that enzyme. The information provided in the article, taken together with the submitted hen study, provides sufficient assurance that methyl parathion is negative for delayed peripheral neuropathy. The Toxicology Chapter will be revised to reflect this conclusion.

C. Appropriateness of the endpoints and the dermal absorption factor

Cheminova objects to the endpoints chosen for risk assessment. Cheminova believes that the endpoints chosen by EPA are too conservative, and suggests alternative studies or endpoints for use in particular risk scenarios. EPA has evaluated Cheminova's proposals and several issues raised by Cheminova were discussed at a meeting of the Hazard Identification Assessment Review Committee (HIARC) on 3/4/99. Results of the re-evaluation are discussed in the attached report of the HIARC (3/23/99), and will be reflected in the revised Toxicology Chapter.

Throughout their comments and data evaluations, Cheminova interpreted cholinesterase inhibition findings according to JMPR/WHO guidelines. This resulted in interpretations of toxicological significance which varied from those of EPA. As discussed above, EPA's interpretation of the cholinesterase inhibition findings in the toxicology studies for methyl parathion was conducted in accordance with EPA policy.

Cheminova believes that the dermal absorption factor selected by EPA, for use when oral endpoints are used for dermal risk assessments, is too high (100%). Several studies were submitted in support of an alternative dermal absorption factor, estimated by Cheminova to be between 10-25%. Cheminova states that they are conducting additional toxicology studies which Cheminova believes will be more appropriate for use in risk assessment for dermal endpoints. EPA believes the appropriate dermal absorption factor to be 100%, based on a comparison of findings in rats and rabbits from oral and dermal studies. This decision was reaffirmed in the HIARC meeting of 3/4/99 (see report, dated 3/23/99). When additional data are submitted, relevant endpoints will be re-evaluated as appropriate. A 5-day dermal toxicity study in the rat was submitted in late May 1999. The study and its accompanying pathology report have been reviewed and the study was found to be unacceptable, since a NOAEL for cholinesterase inhibition was not found and flaws in the study design preclude an accurate assessment of the neuropathy.

D. Retention of the FQPA factor

Cheminova objects to the EPA recommendation for retention of the full 10x FQPA safety factor for protection of infants and children. Their rationale coincides for the most part with that used in their objection to the requirement of a developmental neurotoxicity study (see below). Cheminova also believes that the absence of a requested developmental neurotoxicity study should not be used in support of the retention of the full 10x FQPA Safety Factor (citing IWG Issue paper, June 98). EPA believes that considerable uncertainty remains concerning possible effects of methyl parathion on developing organisms, as described in the Toxicology Chapter, HIARC, and FQPA Safety Factor Committee documents. Since FQPA allows removal of the extra 10x safety factor only in the presence of reliable data documenting safety for the developing organism, EPA is required to retain the factor in the case of methyl parathion.

Cheminova objects to the requirement that a developmental neurotoxicity study be conducted. Cheminova 1) contends that there is no evidence of increased sensitivity in the Guideline studies, 2) disputes the interpretation or relevance of several literature studies cited by EPA, and 3) disputes the relevance of neuropathological findings for assessing the potential for developmental effects of methyl parathion. Cheminova states that the lack of increased sensitivity detected in Guideline studies should be given greater weight in the weight-of-evidence evaluation rather than contrary or equivocal evidence of increased sensitivity in non-guideline literature studies. Cheminova also contends that evidence of increased sensitivity of young organisms exposed to high doses of methyl parathion (seen in several literature studies) is irrelevant to the assessment of possible increased sensitivity to low dose exposures (in part due to differences in metabolic capabilities of developing as opposed to adult organisms). Cheminova also believes literature studies using subcutaneous or intraperitoneal administration of test substances are not relevant to the assessment of effects following oral, dermal, or inhalation exposure. EPA agrees, as noted in the draft risk assessment, that there is no evidence of increased sensitivity in the submitted Guideline studies with methyl parathion. However, several aspects of nervous system development, in particular functional development of the nervous system, are not assessed in the Agency's current Guideline studies. Though EPA agrees that findings of possible increased sensitivity of developing organisms in the open literature studies are not definitive, these findings (as cited in the draft risk assessment), in combination with the findings of irreversible neurological lesions in multiple guideline studies, are sufficient to raise concern and cause uncertainty regarding possible effects of methyl parathion on developing organisms. The data generated in the required developmental neurotoxicity study will address this uncertainty and allow a more reliable assessment of possible adverse effects of methyl parathion on the developing organism.

IV. RESIDUE CHEMISTRY/DIETARY EXPOSURE

A. Plant and Animal Metabolism Data

EPA acknowledges receipt of the following new residue chemistry data submitted in support of the reregistration of methyl parathion: (i) lettuce metabolism data (MRID 44669501) and (ii) additional goat and hen metabolism data (letter dated 2/2/98). These data are under review and will be used in the residue chemistry science assessments and dietary risk assessment analyses for methyl parathion as the Agency deems appropriate. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the dietary exposure estimates used in the dietary risk assessments for methyl parathion. No new methyl parathion residues of concern were identified in the subject studies. Pending acceptance of these new metabolism data to satisfy guideline requirements, no additional plant and animal metabolism data will be required to support the reregistration of methyl parathion. The registrant should resubmit the goat and hen metabolism data (letter dated 2/2/98) cited above through the MRID process.

EPA has considered the registrants' comments concerning the need for residue chemistry data concerning *p*-nitrophenol and continues to recommend that future plant and animal magnitude of the residue studies include data depicting residues of *p*-nitrophenol resulting from the use of methyl parathion.

B. Analytical Methods - Plant and Animal

Since the proposed enforcement method(s) is/are the FDA multiresidue testing protocol(s), an independent laboratory validation (ILV) is not required.

In conjunction with the ruminant and poultry feeding studies, the registrants must provide data validating the analytical method(s) used for determining methyl parathion, methyl paraoxon, *p*-nitrophenol, and amino-paraoxon-methyl in meat, milk, poultry, and eggs. If the feeding studies indicate that tolerances are necessary for residues in animal commodities, then the registrants must propose an enforcement method for determining the residues of concern in animal commodities which must be regulated.

C. Storage Stability Data

EPA acknowledges receipt of the following new residue chemistry data submitted in support of the reregistration of methyl parathion: storage stability data on almond, apple, grape, and peach commodities (MRIDs 44632602, 44643602, 444413403, and 44413301, respectively). These data are under review and will be used in the residue chemistry science assessments and dietary risk assessment analyses for methyl parathion as the Agency deems appropriate. Pending acceptance of these new data to satisfy guideline requirements, no additional storage stability data on plant commodities will be required to support the reregistration of methyl parathion.

Data depicting the storage stability of methyl parathion residues of concern in animal commodities are required in conjunction with the ruminant and poultry feeding.

D. Magnitude of the Residue Data - Plant Commodities

EPA acknowledges receipt of the following new residue chemistry data submitted in support of the reregistration of methyl parathion: (i) almond field trial data (MRID 44632601), (ii) apple field trial data (MRIDs 44413501 and 44413502), (iii) bean field trial data (MRID 43967301), (iv) cherry field trial data (MRID 44622501 and 44622502), (v) cottonseed field trial data (MRID 44430601), (vi) field corn field trial data (MRID 44398301), (vii) grape field trial data (MRIDs 44413401 and 44413402), (viii) hops field trial data (MRID 44501201), (ix) pecan field trial data (MRID 43760901), (x) peanut field trial data (MRID 44620301 and 44620302), (xi) rice field trial data (MRID 44643601), (xii) wheat forage, hay, and straw magnitude of the residue data (MRID 41818502 and 41560001), (xiii) magnitude of the residue data on the aspirated grain fractions (AGF) of wheat (MRID 44794501), and (xiv) peanut processing data (MRID 44620303). These data are under review and will be used in the residue chemsitry science assessments and dietary risk assessment analyses for methyl parathion as the Agency deems appropriate.

EPA understands that Cheminova has committed to generate alfalfa field trial data, grass field trial data, cotton gin by-product magnitude of the residue data, and sunflower seed processing data in support of the registration of the EC formulation of methyl parathion.

EPA undertands that Elf Atochem has committed to generate potato field trial data, onion field trial data, soybean field trial data, cotton gin by-product magnitude of the residue data, and plum processing data in support of the reregistration of the Mcap formulation of methyl parathion. Potato data will be translated to support the use of the Mcap formulation of methyl parathion on sweet potatoes and yams.

Additional residue chemistry data are required to support the reregistration of methyl parathion which the registrants (Cheminova and Elf Atochem) have not committed to generate. Additional sugar beet top and turnip top magnitude of the residue data are required to support the reregistration of the EC formulation of methyl parathion. Additional rice straw magnitude of the residue data are required to support the reregistration of the Mcap formulation of methyl parathion. [Note: Apple field trial data will not be translated to support the use of the Mcap formulation of methyl parathion on pears.] Additional cotton field trial data reflecting the maximum ULV application rates (using vegetable oil as a diluent) to cotton with the EC formulation of methyl parathion are required to support the SLN registration for use on cotton in TX (TX97000600).

The need for additional aspirated grain fractions (AGF) magnitude of the residue data to support the reregistration of methyl parathion is under consideration and clarification concerning the need for these data will be provided in the revised Residue Chapter of the Methyl Parathion RED.

E. Magnitude of the Residue Data - Animal Commodities

Reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs remain outstanding. No tolerances have been established for residues of methyl parathion in animal commodities, although tolerances have been established on numerous animal feed items. EPA understands that the registrants have committed to generate these data.

V. OCCUPATIONAL AND RESIDENTIAL EXPOSURE

EPA acknowledges receipt of the Natural Resources Defense Counsel (NRDC), Consumers' Union (CU), and Cheminova's comments concerning the occupational exposure and risk assessment for methyl parathion. Information provided in the comments will be taken into consideration during EPA's revision of the occupational and residential exposure and risk assessment for methyl parathion. EPA also intends to reconsider the potential exposures to bystanders from spray drift, discussed in CU's comments, in the revised risk assessment, as well as the potential for exposures from use in residential settings.

EPA's revised risk assessment will address many of the concerns expressed by Cheminova. However, it should be noted that the exposure and risk assessments will be based on data currently available to the Agency (e.g., current labels for **all** active registrations, exposure and toxicity data) and on current science policy decisions. Some of the proposed use patterns, where appropriate, will also be incorporated into the revised exposure and risk assessments.

VI. RISK ASSESSMENT/CHARACTERIZATION

A. General

During reregistration of any pesticide, the Office of Pesticide Programs is required to consider all supported registered uses of the chemical. Registered uses and their restrictions, as defined on the labels, are expected to be adhered to. Unregistered uses (illegal uses, accidents, etc.) are not covered under reregistration. Methyl parathion is a restricted use chemical and may only be used by certified applicators. There are no registered residential uses, indoors or outdoors. The Agency will, however, work with the registrants to develop precise label language to prohibit outdoor uses around residences and schools, even by certified applicators. Reported or discovered violations of registered label uses are handled by the appropriate authorities; the Food and Drug Administration, U.S. Department of Agriculture, or the EPA Enforcement Office.

In accordance with current EPA policy (effective 03/11/99) the acute and chronic dietary endpoints are to be expressed as acute Population Adjusted Dose ($_a$PAD) and chronic PAD ($_c$PAD), and no longer as an adjusted Reference Dose (RfD). The RfD is the acute or chronic NOAEL ÷ Uncertainty Factor (UF). Generally, a UF of 100 is applied for intra- and inter-species differences. PAD = acute or chronic RfD ÷ FQPA factor. This will apply whether the FQPA factor is retained (10x or 3x) or not (1x). Occupational, residential (when applicable), by-stander, and the aggregate risk will still be expressed as the Margin of Exposure (MOE). MOE = NOAEL ÷ exposure.

Current EPA policy, determined by the FQPA Safety Factor Committee (04/15/98), directs that worker risk assessments are not considered under FQPA. Therefore, the FQPA factor (10x) for methyl parathion is not applied to the assessment for worker risk. However, when it is appropriate to conduct a risk assessment for residential exposures and by-standers, and data are available to do so, the FQPA factor is applied.

B. Endpoints

1. Endpoint selection, FQPA factor, dermal absorption

Previously, the HIARC had selected a NOAEL = 0.025 mg/kg/d from an acute neurotoxicity study for use in acute dietary, and short- and intermediate-term occupational risk assessment (HIARC Report, 12/01/97). Following a reevaluation of the endpoints on March 4, 1999, the HIARC determined that the acute dietary, as well as the dermal and inhalation short- and intermediate-term occupational endpoints should be based on a NOAEL of 0.11 mg/kg/d for

inhibition of plasma, brain, and red blood cell cholinesterase and neuropathology seen in a 1 year dietary study in rats (Methyl Parathion - Reevaluation of Dietary Endpoint and Non-dietary Endpoint Selection and Dermal Absorption Factor; Report of the Hazard Identification Assessment Review Committee, March 23, 1999). The HIARC did consider the registrant's proposal for the other endpoints but reaffirmed that the NOAEL = 0.02 mg/kg/d from the 2-year chronic oral study in the rat should be used for the chronic dietary, and long-term dermal and inhalation occupational risk assessment. The HIARC also reaffirmed that the dermal absorption factor for methyl parathion would continue to be 100%. The FQPA factor (10x) is retained and the inhalation absorption factor (100%) is unchanged. Changes in the endpoint selection will be reflected in the revised risk assessment.

2. Revised endpoints

REVISED METHYL PARATHION ENDPOINTS 03/04/99				
Exposure Duration	**Exposure Route**	**Endpoint**		**Comments**
		Dose	**Effect**	
Acute - PAD	Dietary	$_{a}$PAD = 0.00011 mg/kg/d	Neuropathology & inhibition of brain, plasma, & red blood cell (RBC) cholinesterase (ChE)	NOAEL = 0.11 mg/kg/d. Based on neuropathology & inhibition of brain, plasma, and RBC ChE occurring at 0.53 mg/kg/d. Systemic toxicity was seen at the highest dose, 2.2 mg/kg/d. One year dietary study in rats. Uncertainty factor (UF) of 100 applied for intra & inter species differences & an additional safety factor of 10X retained by the FQPA Safety Factor Committee for FQPA.
Chronic - PAD	Dietary	$_{c}$PAD = 0.00002 mg/kg/d	Systemic toxicity, neuropathology, & inhibition of RBC ChE at the LOAEL	NOAEL = 0.02 mg/kg/d. Based on systemic toxicity, neuropathology, & RBC ChE inhibition occurring at 0.21 mg/kg/d. Inhibition of plasma and brain ChE occurred at higher doses. Retinal degeneration and clinical signs occurred at the highest dose. 2-Yr chronic feeding study in rats. UF of 100 applied for intra & inter species differences & an additional safety factor of 10X retained by the FQPA Safety Factor Committee for FQPA.
Short-term (1-7 days) Occupational	Dermal	NOAEL = 0.11 mg/kg/d	Neuropathology & inhibition of brain, plasma, & RBC ChE	Same endpoint as Acute PAD. Although a 21-day dermal study in the rabbit is available, it was not selected. See Hazard ID SARC memo 12/01/97. Dermal absorption rate assumed to be 100% (Revisited 02/14/99, 03/04/99). UF of 100 applied for intra & inter species differences.

Intermediate-term (7 - 90 days) Occupational	Dermal	NOAEL = 0.11 mg/kg/d	Neuropathology & inhibition of brain, plasma, & RBC ChE	Same endpoint as Acute PAD. Long term dermal study not available. Dermal absorption rate assumed to be 100%. UF of 100 applied for intra & inter species differences.
Chronic (>several months) Occupational	Dermal	NOAEL = 0.02 mg/kg/d	Systemic toxicity, neuropathology, & inhibition of RBC ChE at the LOAEL	Same endpoint as Chronic PAD. Long term dermal study not available. Dermal absorption rate assumed to be 100%. UF of 100 applied for intra & inter species differences.
Short- & Intermediate-term Occupational	Inhalation	NOAEL = 0.11 mg/kg/d	Neuropathology & inhibition of brain, plasma, & RBC ChE	Same endpoint as Acute PAD. Due to high toxicity seen in acute inhalation study, 100% absorption is assumed. UF of 100 applied for intra & inter species differences.
Long-term Occupational	Inhalation	NOAEL = 0.02 mg/kg/d	Systemic toxicity, neuropathology, & inhibition of RBC ChE at the LOAEL	Same endpoint as Chronic PAD. Due to high toxicity seen in acute inhalation study, 100% absorption is assumed. UF of 100 applied for intra & inter species differences.

C. Dietary (food) risk

In response to the registrants' many comments concerning the preliminary dietary risk assessments for methyl parathion, EPA is currently conducting TIER 3 dietary risk assessments for methyl parathion, substantially refining the previously issued preliminary dietary risk assessments for methyl parathion. We acknowledge receipt of the registrant's TIER 3 chronic and acute dietary risk assessment reports and have used the information contained therein as EPA deemed appropriate.

D. Drinking water risk

Direct drinking water data for methyl parathion are not readily available. While the Agency's Office of Water has established a lifetime health advisory (HA) of 2 ppb, methyl parathion does not have an established Maximum Contaminant Level, and is not included on the Unregulated Contaminant Monitoring List. Therefore, public drinking water supply systems are not required to analyze for methyl parathion. Consequently, the Agency will rely on simulation

models and limited surface- and ground-water monitoring data for the revised risk assessment.

The EPA's screening-level assessments with the GENEEC and SCI-GROW models use the highest label application rate for a pesticide to provide worst-case estimates in surface and ground water. Even with the refinements provided in the PRZMS/EXAMS model, the estimates are still considered over-estimates and screening level. EPA considers the drinking water risk assessment using the over-estimates from models protective of any potential exposures to a chemical from water. Hence, drinking water exposures are not expected to be higher than the models predict. Limited available monitoring data for applications to rice and cotton indicate water levels below EPA's modeling estimates. Specific comments about the derivation of the drinking water estimates will be addressed in the environmental fate and effects portion of this document.

When the Preliminary EPA Chapter (09/01/98) was written, drinking water estimates derived from worst case models with some refinements were used; GENEEC & PRZMS/EXAMS for acute and SCI-GROW for chronic, and some monitoring data. Though those over-estimates indicated potential risks for which the Agency had concerns, they were, **relative to food consumption**, a much lower contributor to the overall dietary risk calculated at the time. Updated, additional monitoring data, though limited, do indicate that residues of methyl parathion are indeed present in water, and these data will be included in the revised risk assessment.

The Agency does consider all children's age groups in the risk assessment but only includes the group with the highest exposure from food for a given pesticide in the risk assessment document. However, the calculated exposures and resulting drinking water risk assessment are the same for all children's groups since the current Agency default body weight and consumption values are 10 kg and 1 litre/day, respectively, for all infants and children. These default values and others are presently under review in the Agency. If the Agency decides to change the default assumptions used, the impact of the changes on the methyl parathion risk assessment will be considered.

E. Occupational risk

See the Occupational and Residential Exposure section.

F. Aggregate risk

Since the preliminary (09/01/98) acute and chronic dietary (food) risk assessments, reported as > 10,000% and > 11,000% of the adjusted RfD (now PAD), respectively, were well above the Agency's level of concern, there was no value added in aggregating the equally preliminary drinking water risks. In other words, the dietary risk to adults and children based on exposures from food alone were above the Agency's level of concern. Therefore, any aggregation of the food and drinking water exposure components would only have served to raise the preliminary risk estimate even more above the Agency's level of concern. The function of the preliminary risk assessment is to serve as a screening tool. In the revised risk assessment the dietary risk (food) from highly refined residue and consumption data will be aggregated with drinking water risks derived from limited monitoring data.

G. Cumulative risk

The Agency is in the process of formulating guidance for conducting cumulative risk assessment. When the guidance is completed, peer reviewed, and finalized, methyl parathion and other organophosphates will be revisited to assess the cumulative effects of exposure to multiple organophosphates.